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UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

PACIRA PHARMACEUTICALS, INC. Plaintiff, v. RESEARCH DEVELOPMENT FOUNDATION, Defendant.	CASE NO.: **COMPLAINT FOR DECLARATORY JUDGMENT** **JURY TRIAL DEMANDED**

Plaintiff Pacira Pharmaceuticals, Inc. ("Pacira") seeks a declaratory judgment against Defendant Research Development Foundation ("RDF") that Pacira owes no royalties to RDF with respect to Pacira's EXPAREL® product made after December 24, 2021.

NATURE OF THE ACTION

1. This is an action for a declaratory judgment pursuant to the Federal Declaratory Judgments Act, 28 U.S.C. §§ 2201–2202, and Rule 57 of the Federal Rules of Civil Procedure.

2. Pacira produces EXPAREL® (bupivacaine liposome injectable suspension), approved by the Food and Drug Administration (FDA) in 2011. EXPAREL® is a first-of-its-kind, single dose local anesthetic administered at the time of surgery to control pain and reduce or eliminate the use of opioids for acute postsurgical pain. The active ingredient in EXPAREL®, bupivacaine, is encapsulated in multivesicular liposomes allowing for gradual release of bupivacaine over time as the lipid membranes are absorbed, prolonging the action of bupivacaine.

3. Pacira, under its former names DepoTech Corporation ("DepoTech") and SkyePharma Inc. ("Skye"), and RDF are signatories to an Assignment Agreement dated February 9, 1994 (the "1994 Agreement") and an Amendment Agreement dated April 15, 2004 (the "2004 Amendment") (collectively the "Agreements").

4. The purpose of the 1994 Agreement was for RDF to assign certain experimental technology and intellectual property to Pacira for it to pursue commercialization and, in exchange, Pacira would make certain royalty payments to RDF under certain conditions. At the time, there was no EXPAREL® product. Instead, during the 1990s, the only Pacira product subject to royalties under the 1994 Agreement was DepoCyt®, which was a cytotoxic anticancer drug. Specifically, DepoCyt® was a cytarabine liposome injection used for the intrathecal treatment of lymphomatous meningitis. Pacira ceased manufacturing DepoCyt® in 2017.

5. A dispute arose in 2003 regarding the scope of the products for which Pacira would owe royalties under the 1994 Agreement. The execution of the 2004 Amendment was an attempt to clarify and resolve the dispute.

6. The 2004 Amendment requires Pacira to pay royalties on products embodying particularly defined inventions that are claimed in certain patents or patent applications for only as long as those particular patents or patent applications are unexpired.

7. However, Pacira and RDF now dispute the interpretation of the 2004 Agreement in conjunction with the 1994 Agreement.

8. It is clear that under the terms of the Agreements, Pacira does not owe any royalties to RDF with respect to Pacira's EXPAREL® product manufactured after December 24, 2021. Specifically, all of the patents encompassing the technology relevant to the Agreements will have expired after December 24, 2021, meaning that Pacira will therefore no longer have an obligation to pay RDF any royalties on Pacira's EXPAREL® product.

9. Despite the plain language in the Agreements, the common-sense interpretation of their terms, and what both parties intended when those Agreements were signed, RDF maintains that, under its interpretation of the terms of the Agreements, Pacira will continue to owe royalties to RDF with respect to Pacira's EXPAREL® product made after December 24, 2021. RDF maintains this position despite the fact that Pacira has independently, and at its own great expense, developed a novel, patented process for making a novel bupivacaine encapsulated multivesicular liposome product, which will be sold as EXPAREL®. RDF also maintains this position despite the fact that all patents relevant to the Agreements will expire on December 24, 2021.

10. Accordingly, Pacira now seeks a declaratory judgment that Pacira does not owe any royalties to RDF with respect to Pacira's EXPAREL® product made after December 24, 2021, under the terms of the Agreements. In the alternative, Pacira seeks a declaratory judgment that any terms of the Agreements that would require Pacira to pay a royalty to RDF with respect to Pacira's EXPAREL® product made after December 24, 2021 are unenforceable as unconscionable and in violation of public policy.

THE PARTIES

11. Pacira is a California corporation with its principal place of business at 5 Sylvan Way, Suite 300, Parsippany, New Jersey 07054.

12. On information and belief, RDF is a Nevada corporation with its principal place of business at 402 North Division Street, Carson City, NV 89703.

JURISDICTION AND VENUE

13. This action arises under the Declaratory Judgment Act, 28 U.S.C. § 2201 et seq.

14. An immediate, real, and justiciable controversy exists between Pacira and RDF as to whether Pacira owes royalties to RDF with respect to Pacira's EXPAREL® product made after

December 24, 2021, under the terms of the Agreements. Because this action presents an actual controversy with respect to Pacira's and RDF's rights and obligations under the Agreements, the Court may grant the declaratory relief sought pursuant to 28 U.S.C. § 2201 et seq.

15. This Court has subject matter jurisdiction over this action pursuant 28 U.S.C. § 1332(a)(1) because it is a dispute between citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

16. This Court has personal jurisdiction over RDF. Among other things, on information and belief, RDF is a Nevada corporation with its principal place of business in this District. Additionally, under the 2004 Amendment, RDF agreed that jurisdiction for any dispute regarding the Agreements would be in Nevada.

17. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) at least because RDF resides in this District. Additionally, under the 2004 Amendment, RDF agreed that venue for any dispute regarding the Agreements would be in Nevada.

FACTUAL BACKGROUND

I. The 1994 Agreement

18. Pacira, under its former name DepoTech, and RDF are signatories to the 1994 Agreement.

19. Under the 1994 Agreement, RDF assigned DepoTech certain "Assigned Proprietary Property," giving DepoTech the exclusive rights to, among other things, make, manufacture, and sell products employing the Assigned Proprietary Property. By its own terms, the 1994 Agreement assigned "no other, further, or different property or rights" except for those provided in the 1994 Agreement.

20. Under the 1994 Agreement, DepoTech was to pay RDF, during the term of the 1994 Agreement, a royalty on Gross Revenues, where Gross Revenues was a defined term.

21. The term Gross Revenue was defined to include "charges actually collected by DepoTech from sales, rental, lease, licensing, maintenance, or production of a Product," where Product was a defined term.

22. The term Product was defined to mean "a product or portion of a product that where made, used or sold embodies an invention there claimed, or which is specifically intended to be used to practice a method or process there claimed in an Assigned Patent (or a patent application if the resulting Letters Patents would constitute an 'Assigned Patent' hereunder) and which is manufactured and sold by or for DepoTech (or its licensees)," where Assigned Patent was a defined term.

23. The term Assigned Patent was defined to mean "the United States of America and Foreign Patents included within Proprietary Property and any division, reissue, continuation or extension thereof," where Proprietary Property was a defined term.

24. The term Proprietary Property was defined to mean "developments, patent rights, copyrights, as well as all patent applications, techniques, methods, processes, apparatus, products, data, trade secrets, confidential information, improvements thereto, modifications thereof, and Know-How, whether patentable or not, related to the technology described in Exhibit 1 hereto," where Exhibit 1 included a description of Proprietary Property.

25. Exhibit 1 to the 1994 Agreement included within Proprietary Property the patented technology of "Multivesicular Liposomes having a Biologically Active Substance Encapsulated therein the Presence of a Hydrochloride," "Heterovesicular Liposomes," "Cyclodextrin Liposomes Encapsulating Pharmacologic Compounds and Methods for their Use," and "Uniform Spherical Multilamellar Liposomes of Defined and Adjustable Size Distribution" described in certain patents and patent applications.

II. The 2003 Dispute

26. In 2003, a dispute arose between RDF and Pacira, then operating under the name Skye, as to the scope of certain payment obligations under the 1994 Agreement.

27. The 2003 dispute included a dispute over the scope of products and related patents for which royalties were owed to RDF under the 1994 Agreement.

28. For example, RDF and Skye disputed whether Skye was required to pay royalties to RDF under the terms of the 1994 Agreement in connection with multivesicular liposome ("MVL") technology that does not encapsulate a biologically active substance in the presence of a hydrochloride ("No HCl Technology").

29. In order to resolve the dispute between RDF and Skye and to clarify and revise the terms of the 1994 Agreement, the parties entered into the 2004 Amendment.

III. The 2004 Amendment

30. Pacira, under its former name Skye, and RDF are signatories to the 2004 Amendment, which was executed April 15, 2004.

31. The 2004 Amendment states that the "parties wish to clarify and revise the terms of the" 1994 Agreement. The effect of the 2004 Amendment was to modify certain parts of the 1994 Agreement such that the Agreements together define the rights and obligations between Pacira and RDF.

32. Under the 2004 Amendment, the term "Proprietary Property" was defined to mean "Skye's multivesicular liposome DepoFoam technology which consists of microscopic, spherical particles composed of multiple non-concentric aqueous chambers encapsulating the biologically active substance therein in the presence or absence of any acid or salt or other compound (the 'DepoFoam Technology')," i.e., including the No HCl Technology and related patents. Under the 2004 Amendment "[s]uch DepoFoam Technology shall also include (a) the Assigned Proprietary Property or Improvements as defined under the 1994 Agreement, and/or (b) existing and future patent or proprietary rights of Skye in DepoFoam Technology whether or not covered by or subject to the Assignment Agreement," where Assigned Proprietary Property and Improvements were defined terms in the 1994 Agreement.

33. Under the 1994 Agreement, the term Improvements was defined to mean "any improvement and/or modification of the Assigned Proprietary Property that comes within the claims of the Assigned Patents." The term Assigned Proprietary Property was defined to mean "the Proprietary Property, including the Patent Rights, rights in Patents, and Know-how, all of which are assigned hereunder to DepoTech."

34. The last remaining patent covered by the Agreements is United States Patent No. 9,585,838 (the "'838 Patent"), entitled "Production of Multivesicular Liposomes," which was issued by the United States Patent and Trademark Office on March 7, 2017. United States Patent Application No. 11/678,615, which issued as the '838 Patent, was filed on February 25, 2007 and

claims priority to United States Patent Application No. 09/192,064, filed on November 13, 1998, and United States Provisional Application No. 60/064,856, filed on November 14, 1997. Thus, the '838 Patent claims priority to a date prior to the 2004 Amendment.

35. The '838 Patent received a 1,137-day Patent Term Adjustment. It is set to expire on December 24, 2021. The '838 Patent is the last remaining patent that is relevant to the Agreements. When the '838 Patent expires on December 24, 2021, therefore, Pacira's obligation to pay royalties to RDF ceases. The '838 Patent's expiration will mark the culmination of decades of royalties payments Pacira has made to RDF.

36. Patents unrelated to the Assigned Patents and that do not claim a priority back before the date of the 2004 Amendment, i.e., April 15, 2004, are not subject to the Agreements by their plain terms. One such patent *not* relevant to the Agreements is United States Patent No. 11,033,495 (the "'495 Patent"), entitled "Manufacturing of Bupivacaine Multivesicular Liposomes." United States Patent Application No. 17/156,400, which issued as the '495 patent, was filed on January 22, 2021, almost seventeen years after the 2004 Amendment. The '495 Patent does not claim priority to any earlier patent or patent application, nor is it related to any patents or patent applications covered by the Agreements. The '495 patent was issued by the United States Patent and Trademark Office on June 15, 2021.

37. Under the terms of the Agreements, Pacira has no obligation to pay royalties on any product covered by the '495 Patent because this patent is not relevant to the Agreements.

38. Under the terms of the Agreements, Pacira has no obligation to pay royalties on any product covered by the '495 Patent because this novel, patented technology is not subject to the Agreements.

IV. The Manufacture of EXPAREL®

39. Since the 1990s, Pacira has worked on manufacturing MVLs with various active drug ingredients.

40. One such manufacturing process has been used with EXPAREL® product for well over a decade and was FDA approved on October 28, 2011 ("Original Patented Technology"). The

'838 Patent, which expires on December 24, 2021, and claims priority to a 1997 provisional patent application, covers Original Patented Technology.

41. Starting in 2013, almost a decade after the 2004 Amendment was signed, Pacira began independently developing a novel, larger-scale process for the manufacture of EXPAREL® product.

42. After over seven years, many failures, countless hours of work and innovation, and an investment of over $100 million, Pacira succeeded in developing a novel manufacturing process. The novel manufacturing process resulted in a novel MVL product with improved properties such as improved stability. The novel manufacturing process and novel MVL product are collectively referred to herein as "New Patented Technology."

43. RDF did not contribute to this New Patented Technology.

44. In order to protect the novel process and MVL product, i.e., the New Patented Technology, Pacira filed U.S. Patent Application No. 17/156,400 on January 22, 2021, which issued as the '495 patent on June 15, 2021.

45. The New Patented Technology is not an "Improvement" (as defined in the 1994 Agreement) and is not subject to the Agreements.

46. The FDA approved the use of the novel manufacturing process for the commercial manufacture of the novel MVL product in August of 2021.

V. The Current Dispute

47. On August 11, 2021, Thomas Brorby, Chairman, Trustee, and counsel for RDF, sent an email to David Stack, Pacira's CEO, congratulating him on the issuance of the '495 Patent and approval by the FDA for the New Patented Technology.

48. In the August 11, 2021 communication, Thomas Brorby stated "[w]e appreciate . . . your corporate strategy for extending the patent period beyond December 24, 2021."

49. On August 26, 2021, David Stack responded, "We look forward to seeing how commercially successful the new process is and are hopeful that it will provide great value to our shareholders," which includes RDF, "in the future." He also requested clarification as to what Brorby meant by "extending the patent period" and stated that "this new patent provides protection for our new manufacturing process."

50. On September 2, 2021, Thomas Brorby responded and asserted that "the 495 Patent on Exparel effectively replaces the 838 Patent and extends the patent period of the Exparel patent to 2041, resulting in a seamless continuation of our respective rights and obligations under the Assignment Agreement."

51. On September 9, 2021, Anthony Molloy, Pacira's General Counsel, replied and reiterated that "the '495 Patent relates to a new manufacturing process."

52. In the September 9, 2021 communication, Anthony Molloy further stated: "The invention claimed in the new patent was conceived of and filed more than a decade after both the 1994 Assignment Agreement and 2004 Amendment. The '495 Patent provides patent protection for this new process; it does not 'effectively replace' the '838 Patent and/or extend the term of the '838 Patent. As such, there is no connection between the '495 Patent and Pacira's 'obligations under the Assignment Agreement.'"

53. In the September 9, 2021 communication, Anthony Molloy further stated: "Based on our understanding of the 1994 Assignment Agreement and 2004 Amendment, and our mutual understanding upon us successfully extending the term of the '838 Patent, Pacira's royalty obligations to Research Development Foundation will end with the expiration of the '838 Patent in December 2021. The issuance of the new '495 Patent does not change this."

54. On September 14, 2021, Thomas Brorby responded and asserted that the '495 Patent and EXPAREL® product "extend royalty payment obligations of Pacira to RDF at least until 2041." Thomas Brorby also asserted that Pacira's royalty obligations to RDF would continue "[o]n any product which utilizes the DepoFoam Technology" "[s]o long as a patent or patent application which embodies DepoFoam Technology remains unexpired."

55. On September 27, 2021, Anthony Molloy again stated that "Pacira's royalty obligations to RDF will end with the expiration of the '838 Patent in December 2021."

56. On October 7, 2021, Thomas Brorby responded and reiterated his assertion that "RDF is entitled to continue to receive royalties from Exparel after expiration of the '838 patent." Thomas Brorby also asserted that Pacira's royalty obligations could continue, in perpetuity, on any product

which utilizes multivesicular liposome technology so long as a patent or patent application embodying that technology remains unexpired.

57. On November 9, 2021, Anthony Molloy responded and stated that "[t]he plain meaning of the 1994 Agreement and the 2004 Amendment, including the language of Section 1.4 of the 2004 Amendment, do not support your positions. Instead, they demonstrate that royalty obligations to RDF will end with the expiration of the '838 Patent."

58. On November 15, 2021, Thomas Brorby responded and again disagreed with Anthony Molloy's communication.

59. RDF incorrectly asserts that Pacira owes royalties on EXPAREL® product for as long as Pacira generates revenue on the product and has any patent related thereto. Under RDF's incorrect interpretation of the Agreements, Pacira would owe royalties until at least 2041 (and potentially indefinitely), which amounts to at least ***47 years*** of royalty obligations.

60. Under RDF's improper interpretation, RDF seeks to claim royalties with respect to the New Patented Technology independently developed by Pacira, which Pacira spent over seven years and $100 million creating and perfecting.

61. Under RDF's improper interpretation, and contrary to the plain language of the Agreements, RDF further seeks to claim royalties until an indefinite point in the future on technology unrelated to what it initially provided to Pacira.

62. Thus, Pacira and RDF dispute whether Pacira owes royalties to RDF with respect to Pacira's EXPAREL® product made after December 24, 2021.

63. RDF's improper royalty claim would amount to millions of dollars in royalty payments into the future. But because there has yet to be a resolution of the parties' dispute as to whether royalties are owed, Pacira intends to continue paying royalties to RDF on EXPAREL® product after December 24, 2021 under protest.

COUNT 1

(Declaratory Judgment That No Royalties Are Owed Under the Terms of the Agreements)

64. Pacira repeats and realleges each and every allegation contained in paragraphs 1 through 63 of this Complaint as if fully set forth herein.

65. RDF has alleged and continues to allege that Pacira owes royalties to RDF with respect to Pacira's EXPAREL® product made after December 24, 2021.

66. Under a proper interpretation of the Agreements, Pacira does not owe royalties on Pacira's EXPAREL® product made after December 24, 2021, or under New Patented Technology.

67. The Court should enter judgment declaring that Pacira does not owe royalties to RDF with respect to Pacira's EXPAREL® product made after December 24, 2021, or under New Patented Technology, under the terms of the Agreements.

68. As a result of the acts described in the foregoing paragraphs, there exists a substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

69. A judicial declaration is necessary and appropriate so that Pacira may ascertain its rights and obligations regarding the Agreements.

70. Pacira is entitled to a judicial declaration that it does not owe royalties to RDF with respect to Pacira's EXPAREL® product made after December 24, 2021, or under New Patented Technology, under the terms of the Agreements.

COUNT 2

(Declaratory Judgment that Terms of the Agreements are Unenforceable)

71. Pacira repeats and realleges each and every allegation contained in paragraphs 1 through 70 of this Complaint as if fully set forth herein.

72. RDF has alleged and continues to allege that Pacira owes royalties to RDF with respect to Pacira's EXPAREL® product made after December 24, 2021, including through at least 2041. The Court should enter judgment declaring that Pacira does not owe royalties to RDF with respect to Pacira's EXPAREL® product made after December 24, 2021, or under New Patented Technology because any terms of the Agreements are unenforceable as unconscionable and in violation of public policy to the extent they require royalty payments with respect to Pacira's EXPAREL® product made after December 24, 2021 or under New Patented Technology.

73. RDF has asserted that the Agreements "provide that Pacira's payment obligations to RDF will continue: 1. On any product which utilizes the DepoFoam Technology, 2. So long as a patent or patent application which embodies DepoFoam Technology remains unexpired, 3. Regardless of

whether such patent is existing or future, 4. Regardless of whether the patent was developed and/or filed by Pacira or RDF."

74. Upon information and belief, RDF interprets "DepoFoam Technology" to include all multivesicular liposome technology, regardless of when it was created or the particular attributes of the specific multivesicular liposome.

75. Upon information and belief, under RDF's assertions, royalty obligations under the Agreements could extend for an infinite amount of time.

76. Upon information and belief, under RDF's assertions, royalty obligations under the Agreements extend to all multivesicular liposome technology regardless of whether it relates to patented technology provided by RDF or whether it was even in existence at the time the 2004 Amendment was signed.

77. Upon information and belief, under RDF's assertions, royalty obligations could lay dormant and spring into existence with the filing of a new patent application or grant of a new patent years or decades later.

78. To the extent any terms of the Agreements could result in royalty obligations for an infinite amount of time, such terms of the Agreements are unenforceable as unconscionable.

79. To the extent any terms of the Agreements could result in royalty obligations for all multivesicular liposome technology regardless of whether it relates to patented technology provided by RDF or whether it was even in existence at the time the 2004 Amendment was signed, such terms of the Agreements are unenforceable as unconscionable.

80. To the extent any terms of the Agreements could result in royalty obligations lying dormant and springing into existence with the filing of a new patent application or grant of a new patent, such terms of the Agreements are unenforceable as unconscionable.

81. To the extent any terms of the Agreements require Pacira to pay royalties to RDF with respect to Pacira's EXPAREL® product made after December 24, 2021, or under New Patented Technology, such terms of the Agreements are unenforceable as unconscionable.

82. To the extent any terms of the Agreements could result in royalty obligations for an infinite amount of time, such terms of the Agreements are unenforceable as against public policy.

83. To the extent any terms of the Agreements could result in royalty obligations for all multivesicular liposome technology regardless of whether it relates to patented technology provided by RDF or whether it was even in existence at the time the 2004 Amendment was signed, such terms of the Agreements are unenforceable as against public policy.

84. To the extent any terms of the Agreements could result in royalty obligations lying dormant and springing into existence with the filing of a new patent application or grant of a new patent, such terms of the Agreements are unenforceable as against public policy.

85. To the extent any terms of the Agreements require Pacira to pay royalties to RDF with respect to Pacira's EXPAREL® product made after December 24, 2021, or under New Patented Technology, such terms of the Agreements are unenforceable as against public policy.

86. As a result of the acts described in the foregoing paragraphs, there exists a substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

87. A judicial declaration is necessary and appropriate so that Pacira may ascertain its rights and obligations regarding the Agreements.

88. Pacira is entitled to a judicial declaration that any terms of the Agreements that would require Pacira to pay a royalty to RDF with respect to Pacira's EXPAREL® product made after December 24, 2021 or under New Patented Technology are unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Pacira respectfully requests the following:

a) That the Court enter a judgment declaring that Pacira does not owe any royalties to RDF with respect to Pacira's EXPAREL® product made after December 24, 2021, under the terms of the Agreements.

b) That the Court enter a judgment declaring that Pacira does not owe any royalties to RDF with respect to Pacira's EXPAREL® product made using New Patented Technology, under the terms of the Agreements.

c) That the Court enter judgment declaring that any terms of the Agreements that would require Pacira to pay a royalty to RDF with respect to Pacira's EXPAREL® product made after December 24, 2021 or under New Patented Technology are unenforceable.

d) That the Court award a refund of any royalties Pacira pays under protest on Pacira's EXPAREL® product made after December 24, 2021, or under New Patented Technology, and order RDF to repay such.

e) That the Court award Pacira any and all other relief to which Pacira may show itself to be entitled; and

f) That the Court award Pacira any other relief as the Court may deem just, equitable, and proper.

JURY DEMAND

Pacira hereby demands a trial by jury on all issues so triable.

DATED this 23rd day of December, 2021.

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